



## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[Docket ID FEMA-2020-0016]

#### **Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Personal Protective Equipment (PPE) to Respond to COVID-19 Implemented under the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

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**SUMMARY:** The Federal Emergency Management Agency (FEMA) announces the activation of a Plan of Action to establish a National Strategy for the manufacture, allocation, and distribution of Personal Protective Equipment (PPE) to respond to COVID-19 implemented under the Voluntary Agreement for the manufacture and distribution of critical healthcare resources necessary to respond to a pandemic. This Notice contains the text of the Plan of Action.

**FOR FURTHER INFORMATION CONTACT:** Robert Glenn, Office of Business, Industry, Infrastructure Integration, Federal Emergency Management Agency, (202) 212-1666, and email *OB3I@fema.dhs.gov*.

#### **SUPPLEMENTARY INFORMATION:**

##### **Authority**

Section 708 of the Defense Production Act (DPA), 50 U.S.C. 4558, allows the President to provide for the formation of voluntary agreements and plans of action by the private sector to help provide for the national defense. This authority was delegated to

the Secretary of Homeland Security generally in section 401 of Executive Order 13603<sup>1</sup>, “National Defense Resources Preparedness,” and specifically for response to COVID-19 in section 3 of Executive Order 13911<sup>2</sup>, “Delegating Additional Authority Under the Defense Production Act With Respect to Health and Medical Resources To Respond to the Spread of COVID-19.” The Secretary of Homeland Security has delegated these authorities to the FEMA Administrator in Department of Homeland Security (DHS) Delegation 09052 Rev. 00, “Delegation of Defense Production Act Authority to the Administrator of the Federal Emergency Management Agency,” (Jan. 3, 2017), and DHS Delegation 09052 Rev. 00.1, “Delegation of Defense Production Act Authority to the Administrator of the Federal Emergency Management Agency” (Apr. 1, 2020), respectively.

## **Background**

FEMA sought and received approval from the Attorney General, after consultation with the Federal Trade Commission (FTC), to begin consultation with the private sector, as required by Section 708(c)(2). Pursuant to that approval, on May 12, 2020, FEMA posted an announcement of a public meeting and request for comments to develop a Voluntary Agreement in the *Federal Register* (85 FR 28031). FEMA held a public meeting on May 21, 2020, and accepted public comments until June 5, 2020.<sup>3</sup> FEMA received 34 public comments and considered these comments when preparing the Voluntary Agreement.<sup>4</sup>

The Attorney General, in consultation with the Chairman of the Federal Trade Commission, made the required finding that the purpose of the Voluntary Agreement may not reasonably be achieved through an agreement having less anticompetitive effect

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<sup>1</sup> 77 FR 16651 (Mar. 22, 2012).

<sup>2</sup> 85 FR 18403 (Apr. 1, 2020).

<sup>3</sup> The original comment period was extended to allow commentators additional time to respond. FEMA posted notices of extension to [www.regulations.gov](http://www.regulations.gov) under the Docket ID for this notice, FEMA-2020-0016.

<sup>4</sup> Available on [www.regulations.gov](http://www.regulations.gov) under the Docket ID for this notice.

or without any Voluntary Agreement. Pursuant to Sec. 708(f)(1)(B) of the DPA, the Department of Justice separately published this finding in the *Federal Register* on August 17, 2020 as a notice (85 FR 50049). The FEMA Administrator, as the Sponsor of the agreement, certified in writing that the agreement was necessary to help provide for the national defense. FEMA provided notice of the formation and the text of the Voluntary Agreement in the *Federal Register* on August 17, 2020 (85 FR 50035).

On October 13, 2020, FEMA held a virtual meeting to implement the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic (*see* 85 FR 63567). A portion of the meeting was open to the public. One objective of this meeting was to discuss the activation of the first Plan of Action under the Voluntary Agreement to identify more efficient methods of allocating and distributing Personal Protective Equipment to meet national demand and ways of expanding the production of critical healthcare resources, with an initial focus on the manufacture of N95 masks. From this meeting, FEMA incorporated public comments and feedback from the U.S. Department of Justice and the Federal Trade Commission to develop the Plan of Action.

The Attorney General, in consultation with the Chairman of the Federal Trade Commission, made the required finding that the purposes of section 708(c)(1) of the DPA cannot reasonably be achieved without any Plan of Action, or by a plan of action having less anticompetitive effects than the proposed Plan of Action. Pursuant to section 708(f)(1)(B) of the DPA, the Department of Justice is separately publishing this finding in the *Federal Register* as a notice. The FEMA Administrator has certified in writing that this Plan of Action is necessary to help provide for the national defense.

**Text of the Plan of Action to Establish a National Strategy for the manufacture, allocation, and distribution of Personal Protective Equipment (PPE) to respond to COVID-19 implemented under the voluntary agreement for the**

# **MANUFACTURE AND DISTRIBUTION OF CRITICAL HEALTHCARE RESOURCES NECESSARY TO RESPOND TO A PANDEMIC**

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**Preface**

Pursuant to section 708 of the Defense Production Act of 1950 (DPA), as amended (50 U.S.C. § 4558), the Federal Emergency Management Agency (FEMA) Administrator (Administrator), after consultation with the Secretary of the Department of Health and Human Services (HHS), the Attorney General of the United States (Attorney General), and the Chairman of the Federal Trade Commission (FTC), developed a Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic (Voluntary Agreement), 85 FR 50035 (August 17, 2020). The Voluntary Agreement, which operates through a series of Plans of Action, maximizes the manufacture and efficient distribution of Critical Healthcare Resources nationwide to respond to a pandemic by establishing unity of effort between Participants and the Federal Government for integrated coordination, planning, information sharing with FEMA, as authorized by FEMA, and allocation and distribution of Critical Healthcare Resources.

This document establishes a Plan of Action (Plan) for the Manufacture, Allocation, and Distribution of Personal Protective Equipment (PPE) to Respond to COVID-19. This Plan will be implemented under the Voluntary Agreement by several Sub-Committees:

- (1) Sub-Committee to Define COVID-19 PPE Requirements,
- (2) Sub-Committee for N-95 and other Medical Respirators,
- (3) Sub-Committee for Gloves,
- (4) Sub-Committee for Gowns, and
- (5) Sub-Committee for Eye and Facial Coverings.

FEMA may establish additional Sub-Committees under this Plan of Action, so long as:

- (1) The Sub-Committee addresses one specific and well-defined category of PPE;
- and

(2) The Sub-Committee is recommended by the Sub-Committee to Define COVID-19 PPE Requirements.

The purpose of the Plan and the Sub-Committees is to maximize the manufacture and efficient distribution of selected types of critical PPE and create a prioritization protocol for End-Users based upon their demonstrated or projected requirements including geographic and regional circumstances. The primary goal of the Plan is to create a mechanism to immediately meet exigent PPE requests anywhere in the Nation and to ensure that actions to support PPE stockpiling and reserves do not interfere with immediate requirements that would result in an unacceptable risk to healthcare providers or other potential PPE recipients. When the requirements of the Plan are met, it affords Sub-Committee Participants defenses to civil and criminal actions brought under the antitrust laws (or any similar law of any state) for actions taken within the scope of the Plan. The Plan is designed to foster a close working relationship among FEMA, HHS, and Sub-Committee Participants to address national defense needs through cooperative action under the direction and active supervision of FEMA.

## **I. Purpose**

A pandemic may present conditions that pose a direct threat to the national defense of the United States or its preparedness programs such that, pursuant to DPA section 708(c)(1), an agreement to collectively coordinate, plan, and collaborate for the manufacture and distribution of PPE is necessary for the national defense. This Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Personal Protective Equipment (PPE) to Respond to COVID-19 is established under the Voluntary Agreement and establishes five Sub-Committees to oversee and implement the Plan. The Plan and Sub-Committees will optimize the manufacture and the efficient distribution of selected types of critical PPE and create a

prioritization protocol for End-Users based upon their demonstrated or projected requirements and taking into account geographic and regional circumstances for stabilization and reduction of COVID-19 exposure.

## **II. Authorities**

Section 708, Defense Production Act (50 U.S.C. 4558); sections 402(2) & 501(b), Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121-5207); sections 503(b)(2)(B) & 504(a)(10) & (16) of the Homeland Security Act of 2002 (6 U.S.C. 313(b)(2)(B), 314(a)(10) & (16)); sections 201, 301, National Emergencies Act (50 U.S.C. 1601 *et seq.*); section 319, Public Health Service Act (42 U.S.C. 247d); Executive Order (E.O.) 13911, 85 FR 18403 (March 27, 2020); Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Domestic Use, 85 FR 20195 (April 10, 2020). Pursuant to DPA section 708(f)(1)(A), the Administrator certifies that this Plan is necessary for the national defense.

## **III. General Provisions**

### **A. Definitions**

#### **Administrator**

The FEMA Administrator is the Sponsor of the Voluntary Agreement. Pursuant to a delegation or redelegation of the functions given to the President by DPA section 708, the Administrator proposes and provides for the development and carrying out of the Voluntary Agreement, including through the development and implementation of Plans of Action. The Administrator is responsible for carrying out all duties and responsibilities required by 50 U.S.C. 4558 and 44 CFR part 332 and for appointing one or more Chairpersons to manage and administer the Committee and all Sub-Committees formed to carry out the Voluntary Agreement.

#### **Agreement**

The Voluntary Agreement for the Manufacture and Distribution of Critical

## Healthcare Resources Necessary to Respond to a Pandemic (Voluntary Agreement).

### **Allocation**

The process of determining and directing the relative distribution among one or more competing requests from End-Users for the same PPE. Through the Allocation process, FEMA – with participation from Sub-Committee Participants – will assess the actual needs of End-Users and determine how to divide the available and projected supply of PPE to minimize impacts to life, safety, and economic disruption associated with shortages of critical PPE. Allocation will take place only under Exigent Circumstances. FEMA retains decision-making authority for all Allocation under this Plan.

### **Attendees**

Subject matter experts, invited by the Chairperson or a Sub-Committee Chairperson to attend meetings authorized under the Voluntary Agreement or this Plan of Action, to provide technical advice or to represent other government agencies or interested parties. Invitations to attendees will be extended as required for Committee or Sub-Committee meetings and deliberations.

### **Chairperson**

FEMA senior executive(s), appointed by the Administrator, to chair the Committee for the Distribution of Healthcare Resources Necessary to Respond to a Pandemic (Committee). The Chairperson shall be responsible for the overall management and administration of the Committee, the Voluntary Agreement, and Plans of Action developed under the Voluntary Agreement while remaining under the supervision of the Administrator; shall initiate, or approve in advance, each meeting held to discuss problems, determine policies, recommend actions, and make decisions necessary to carry out the Voluntary Agreement; appoint one or more co-Chairpersons to chair the Committee, and otherwise shall carry out all duties and responsibilities



assigned to him. With the approval of the Administrator, the Chairperson may create one or more Sub-Committees, and may appoint one or more Sub-Committee Chairpersons to chair the Sub-Committees, as appropriate.

### **Committee**

Committee for the Distribution of Healthcare Resources Necessary to Respond to a Pandemic established under the Voluntary Agreement.

### **Competitively Sensitive Information**

Competitively Sensitive Information that is shared pursuant to this Plan of Action may include any Document or other tangible thing or oral transmission that contains financial, business, commercial, scientific, technical, economic, or engineering information or data, including, but not limited to

- financial statements and data,
- customer and supplier lists,
- price and other terms of sale to customers,
- sales records, projections and forecasts,
- inventory levels,
- capacity and capacity utilization,
- cost information,
- sourcing and procurement information,
- manufacturing and production information,
- delivery and shipping information,
- systems and data designs, and
- methods, techniques, processes, procedures, programs, codes, or similar information, whether tangible or intangible, and regardless of the method of storage, compilation, or recordation, if the owner thereof has taken reasonable measures to protect the information from disclosure to the public or competitors. These measures may be evidenced by marking or labeling the items as “competitively sensitive information” during submission to FEMA or in the Participant’s customary and existing treatment of such information (regardless of labeling).

All Competitively Sensitive Information provided by a Sub-Committee Participant as described herein is deemed Competitively Sensitive Information, except for Information that:

- a. is published or has been made publicly available at the time of disclosure by the

Sub-Committee Participant;

b. was in the possession of, or was lawfully and readily available to, FEMA from another source at the time of disclosure without breaching any obligation of confidentiality applicable to the other source; or

c. was independently developed or acquired without reference to or reliance upon the Sub-Committee Participant's Competitively Sensitive Information;

Where information deemed Competitively Sensitive Information is required to be disclosed by law, regulation, or court order, the "Competitively Sensitive" (or substantially similar) label will continue to attach to all information and portion(s) of documents that are not made public through the required disclosure.

### **Document**

Any information, on paper or in electronic/audio/visual format, including written, recorded, and graphic materials of every kind, in the possession, custody, or control of the Participant and used or shared in the course of participation in the Voluntary Agreement or a subsequent Plan of Action.

### **End-User**

This includes all direct and ancillary medical support including, but not limited to, hospitals, independent healthcare providers, nursing homes, medical laboratories, dental care providers, independent physician offices, first responders, alternate care facilities and the general public that reasonably represents the totality of the nation's professional or medical response to COVID-19. "End-User" may also include essential workers necessary to maintain or restore critical infrastructure operations, including but not limited to law enforcement, education, food and agriculture, energy, water and wastewater, and public works personnel.

### **Exigent Circumstances**

As determined by the Chairperson, the actual or forecasted shortage of a

particular type or types of PPE which likely cannot be fulfilled via usual market mechanisms for an acute, critical time period, and where immediate and substantial harm is projected to occur from lack of intervention.

### **Pandemic**

A Pandemic is defined as an epidemic that has spread to human populations across a large geographic area that is subject to one or more declarations under the National Emergencies Act, the Public Health Service Act, or the Robert T. Stafford Disaster Relief and Emergency Assistance Act, or if the Administrator determines that one or more declarations is likely to occur and the epidemic poses a direct threat to the national defense or its preparedness programs. For example, Coronavirus Disease 2019 (COVID-19).

### **Participant**

An individual, partnership, corporation, association, or private organization, other than a federal agency, that has substantive capabilities, resources or expertise to carry out the purpose of the Voluntary Agreement, that has been specifically invited to participate in the Voluntary Agreement by the Chairperson, and that has applied and agreed to the terms of the Voluntary Agreement. “Participant” includes a corporate or non-corporate entity entering into the Voluntary Agreement and all subsidiaries and affiliates of that entity in which that entity has 50 percent or more control either by stock ownership, board majority, or otherwise. The Administrator may invite Participants to join the Voluntary Agreement at any time during its effective period.

### **Personal Protective Equipment (PPE)**

Objects that provide measures of safety protection for healthcare workers, first responders, critical infrastructure personnel and/or the general public for the response to the Pandemic. These PPE items may include, but are not limited to, face coverings, filtering facepiece respirators, face shields, isolation and surgical

gowns, examination and surgical gloves, suits, and foot coverings.

### **Plan of Action (Plan)**

This document. A documented method, pursuant to 50 U.S.C. 4558(b)(2), proposed by FEMA to implement a particular set of activities under the Voluntary Agreement, through a Sub-Committee focused on a particular Critical Healthcare Resource, or pandemic response workstream or functional area necessary for the national defense.

### **Plan of Action Agreement**

A separate commitment made by Participants upon invitation and agreement to participate in a Plan of Action as part of one or more Sub-Committees. Completing the Plan of Action Agreement confers responsibilities on the Participant consistent with those articulated in the Plan of Action and affords Participants a defense against antitrust claims under section 708 for actions taken to develop or carry out the Plan of Action and the appropriate Sub-Committee(s), as described in Section IV below.

### **Representatives**

The representatives the Administrator identifies and invites to the Committee from FEMA, HHS, and other federal agencies with equities in this Plan, and empowered to speak on behalf of their agencies' interests. The Attorney General and the Chairman of the FTC, or their delegates, may also attend any meeting as a Representative.

### **Sub-Committee**

A body formed by the Administrator from select Participants to implement a Plan of Action.

### **Sub-Committee Chairperson**

FEMA official, appointed by the Chairperson, to chair a Sub-Committee to implement a Plan of Action. The Sub-Committee Chairperson shall be responsible for

the overall management and administration of the Sub-Committee in furtherance of this Plan of Action while remaining under the supervision of the Administrator and the Chairperson.

### **Sub-Committee Members**

Collectively the Sub-Committee Chairperson(s), Representatives, and Sub-Committee Participants. Jointly responsible developing and executing this Plan.

### **Sub-Committee Participant**

A subset of Participants of the Committee, that have been specifically invited to participate in a Sub-Committee by the Sub-Committee Chairperson, and that have applied and agreed to the terms of this Plan and signed the Plan of Action Agreement. The Sub-Committee Chairperson may invite Participants in the Committee to join a Sub-Committee as a Sub-Committee Participant at any time during the Plan's effective period.

## **B. Plan of Action Participation**

This Plan will be carried out by a subset of the Participants in the Voluntary Agreement through several Sub-Committees:

- (1) Sub-Committee to Define COVID-19 PPE Requirements,
- (2) Sub-Committee for N-95 and other Medical Respirators,
- (3) Sub-Committee for Gloves,
- (4) Sub-Committee for Gowns, and
- (5) Sub-Committee for Eye and Facial Coverings.

FEMA may establish additional Sub-Committees under this Plan of Action, so long as:

- (1) The Sub-Committee addresses one specific and well-defined category of PPE;  
and
- (2) The Sub-Committee is recommended by the Sub-Committee to Define COVID-19 PPE Requirements.

Each Sub-Committee will consist of the (1) Sub-Committee Chairperson(s), (2) Representatives from FEMA, HHS, the Department of Justice (DOJ), and other federal agencies with equities in this Plan, and (3) Sub-Committee Participants that have substantive capabilities, resources or expertise to carry out the purpose of this Plan and have signed the Plan of Action Agreement. The Chairperson shall invite Sub-Committee Participants who, in his or her determination, are reasonably representative of the appropriate industry or segment of such industry. Other Attendees – invited by the Sub-Committee Chairperson as subject matter experts to provide technical advice or to represent the interests of other government agencies or interested parties – may also participate in Sub-Committee meetings. The naming of these Sub-Committees does not commit the Administrator to creating them unless and until circumstances dictate.

#### **C. Effective Date and Duration of Participation**

This Plan is effective immediately upon satisfaction of the requirements of DPA section 708(f)(1). This Plan shall remain in effect until terminated in accordance with 44 CFR 332.4. It shall be effective for no more than five (5) years from August 17, 2020, when the requirements of DPA section 708(f)(1) were satisfied for the Voluntary Agreement, unless otherwise terminated pursuant to DPA section 708(h)(9) and 44 CFR 332.4 or extended as set forth in DPA section 708(f)(2). No action may take place under this Plan until it is activated, as described in Section III(E), below.

#### **D. Withdrawal**

Participation in the Plan is voluntary, as is the acceptance of most obligations under the Plan. Sub-Committee Participants may withdraw from this Plan or from an individual Sub-Committee at any point, subject to the fulfillment of obligations previously agreed upon by the Participant prior to the date of withdrawal. Note that the obligations outlined in V.B regarding information management and associated

responsibilities apply once a party has shared or received information through a Sub-Committee, and remain in place after the party's withdrawal from the Sub-Committee or Plan. If a Sub-Committee Participant indicates an intent to withdraw from the Plan due to a modification or amendment of the Plan (described below), the Sub-Committee Participant will not be required to perform actions directed by that modification or amendment. *Withdrawal from the Plan will automatically trigger withdrawal from all Sub-Committees; however, a Participant may withdraw from a Sub-Committee without also withdrawing from the Plan or other Sub-Committees.* To withdraw from the Plan or from an individual Sub-Committee, a Participant must provide written notice to the Administrator at least fifteen (15) calendar days prior to the effective date of that Sub-Committee Participant's withdrawal specifying the scope of withdrawal. Following receipt of such notice, the Administrator will inform the other Sub-Committee Participants of the date and the scope of the withdrawal.

Upon the effective date of the withdrawal from the Plan, the Sub-Committee Participant must cease all activities under the Plan. Upon the effective date of the withdrawal from one or more Sub-Committee(s), the Sub-Committee Participant must cease all activities under the Plan that pertain to the withdrawn Sub-Committee(s).

#### **E. Plan of Action Activation and Deactivation**

The Administrator, in consultation with the Chairperson and Sub-Committee Chairperson, will invite a select group of Participants in the Voluntary Agreement to form the following Sub-Committees, which will be responsible for implementing this Plan:

- (1) Sub-Committee to Define COVID-19 PPE Requirements,
- (2) Sub-Committee for N-95 and other Medical Respirators,
- (3) Sub-Committee for Gloves,

- (4) Sub-Committee for Gowns, and
- (5) Sub-Committee for Eye and Facial Coverings.

FEMA may establish additional Sub-Committees under this Plan of Action, so long as:

- (1) The Sub-Committee addresses one specific and well-defined category of PPE;  
and
- (2) The Sub-Committee is recommended by the Sub-Committee to Define COVID-19 PPE Requirements.

This Plan will be activated for each invited Participant when the Participant executes a Plan of Action Agreement, and a Participant may not participate in a Sub-Committee until the Plan of Action Agreement is executed. Participants will be invited to join this Plan at the discretion of the Chairperson or the Sponsor to the Voluntary Agreement. Participants will be further invited to attend specific meetings of one or more Sub-Committees at the discretion of the Chairperson.

#### **F. Rules and Regulations**

Sub-Committee Participants acknowledge and agree to comply with all provisions of DPA section 708, as amended, and regulations related thereto which are promulgated by FEMA, the Department of Homeland Security, HHS, the Attorney General, and the FTC. FEMA has promulgated standards and procedures pertaining to voluntary agreements in 44 CFR part 332. The Administrator shall inform Participants of new rules and regulations as they are issued.

#### **G. Modification and Amendment**

The Administrator, after consultation with the Attorney General and the Chairman of the FTC, may terminate or modify, in writing, this Plan at any time. The Attorney General, after consultation with the Chairman of the FTC and the Administrator, may terminate or modify, in writing, this Plan at any time. Sub-Committee Participants may propose modifications or amendments to the Plan or to the Sub-Committees at any time.



Where possible, material modifications to the Plan or a Sub-Committee will be subject to a 30 calendar day delayed implementation and opportunity for notice and comment by Sub-Committee Participants to the Chairperson. This delayed implementation period may be shortened or eliminated if the Administrator deems it necessary. The Administrator shall inform Sub-Committee Participants of modifications or amendments to the Plan or to the Sub-Committees as they are proposed and issued.

The Administrator, after consultation with the Attorney General and the Chairman of the FTC, may remove Sub-Committee Participants from the Plan or from a Sub-Committee at any time. The Attorney General, after consultation with the Chairman of the FTC and the Administrator, may remove Sub-Committee Participants from this Plan or from a Sub-Committee at any time. If a Participant is removed from the Plan or from a Sub-Committee, the Participant may request written notice of the reasons for removal from the Chairperson, who shall provide such notice in a reasonable time period.

#### **H. Expenses**

Participation in this Plan or in a Sub-Committee does not confer funds to Sub-Committee Participants, nor does it limit or prohibit any pre-existing source of funds. Unless otherwise specified, all expenses, administrative or otherwise, incurred by Sub-Committee Participants associated with participation in this Plan or a Sub-Committee shall be borne exclusively by the Sub-Committee Participants.

#### **I. Record Keeping**

Each Sub-Committee Chairperson shall have primary responsibility for maintaining records in accordance with 44 CFR part 332 and shall be the official custodian of records related to carrying out this Plan. Each Sub-Committee Participant shall maintain for five years all minutes of meetings, transcripts, records, documents, and other data, including any communications with other Sub-Committee Participants or with

any other member of the Sub-Committee, including drafts, related to the carrying out of this Plan or incorporating data or information received in the course of carrying out this Plan. Each Sub-Committee Participant agrees to produce to the Administrator, the Attorney General, and the Chairman of the FTC upon request any item that this section requires the Participant to maintain. Any record maintained in accordance with 44 CFR part 332 shall be available for public inspection and copying, unless exempted on the grounds specified in 5 U.S.C. 552(b)(1), (3) or (4) or identified as privileged and confidential information in accordance with DPA section 705(d), and 44 CFR 332.5.

#### **IV. Antitrust Defense**

Under the provisions of DPA subsection 708(j), each Sub-Committee Participant in this Plan shall have available as a defense to any civil or criminal action brought for violation of the antitrust laws (or any similar law of any State) with respect to any action to develop or carry out this Plan, that such action was taken by the Sub-Committee Participant in the course of developing or carrying out this Plan, that the Sub-Committee Participant complied with the provisions of DPA section 708 and the rules promulgated thereunder, and that the Sub-Committee Participant acted in accordance with the terms of the Voluntary Agreement and this Plan. Except in the case of actions taken to develop this Plan, this defense shall be available only to the extent the Sub-Committee Participant asserting the defense demonstrates that the action was specified in, or was within the scope of, this Plan and within the scope of the appropriate Sub-Committee(s), including being taken at the direction and under the active supervision of FEMA.

This defense shall not apply to any actions taken after the termination of this Plan. Immediately upon modification of this Plan, no defense to antitrust claims under Section 708 shall be available to any subsequent action that is beyond the scope of the modified Plan. The Sub-Committee Participant asserting the defense bears the burden of proof to establish the elements of the defense. The defense shall not be available if the person

against whom the defense is asserted shows that the action was taken for the purpose of violating the antitrust laws.

## **V. Terms and Conditions**

As the sponsoring agency, FEMA will maintain oversight over Sub-Committee activities and direct and supervise actions taken to carry out this Plan, including by retaining decision-making authority over actions taken pursuant to the Plan to ensure such actions are necessary to address a direct threat to the national defense. The Attorney General and the Chairman of the FTC will monitor activities of the Sub-Committees to ensure they execute their responsibilities in a manner consistent with this Plan and their actions have the least anticompetitive effects possible.

### **A. Plan of Action Execution**

This Plan will be used to support the following objectives to respond to a Pandemic by maximizing the manufacture and efficient distribution of selected types of critical PPE and creating a prioritization protocol for End-Users based upon their demonstrated or projected requirements and taking into account geographic and regional circumstances. Each Sub-Committee will undertake the following Objectives for the PPE item(s) within its area of jurisdiction.

#### **1. Objectives**

- (1) Optimize the timely production of sufficient quantities of PPE to reduce loss of life and transmission of the COVID-19 virus.
- (2) Ensure PPE is distributed effectively across the whole community nationally based on risk.
- (3) Balance restoration and maintenance of the nation's stockpile of PPE with near-term requirements.
- (4) Establish a process for FEMA Allocation of PPE nationwide.

- (5) Ensure ongoing competition in the manufacture and distribution of PPE to the greatest extent possible under the DPA.

## **2. Actions**

Sub-Committee Participants may be asked to support these objectives by taking the following specific actions:

- (1) Assist the Chairperson in identifying which types of critical PPE should be included within each Sub-Committee. Identification will be based upon each item's importance to the national response to COVID-19 and whether it can be reasonably inferred, based upon the best evidence available, that that current and projected supply measured against current and projected demand may not adequately meet the PPE requirements to all identified End-Users or regional or geographic areas of the country as result of measures taken to respond to COVID-19.
- (2) Provide input to the Chairperson in creating a prioritized list of PPE End-Users by categories for each type of critical PPE identified by each Sub-Committee, and ascertaining the relative demand and supply of PPE among and within those End User categories. Prioritization shall be decided by the Chairperson, based upon each item's importance, reflecting the consensus views of the Sub-Committee Members that it represents the most effective way to save lives and prevent the transmission of the COVID-19 virus. This list may be updated throughout the life of the Plan of Action based upon either short term or long-term demands. These categories should be considered holistically in terms of the Whole-of-Nation response to COVID-19.
- (3) Evaluate the domestic supply of PPE and identify when the expansion of the domestic manufacture of PPE may be necessary, as directed and decided by the Chairperson.
- (4) Provide information, assist, and validate, as necessary as decided by the

Chairperson, demand projections for PPE.

(5) Create a process for and collaborate in the evaluation of competing claims for PPE from End-Users.

(6) Prepare a general strategy to accomplish the activities listed in V(A)(2)(7) below regarding activities in Exigent Circumstances consistent with the decisions made by the Chairperson.

(7) In Exigent Circumstances, with review and concurrence in all possible instances by DOJ in consultation with FTC:

- Facilitate maximum availability of PPE to the nation or particular geographies by deconflicting overlapping demands from the collective Participants' customer base, as directed and decided by the Chairperson.

- Facilitate maximum availability of PPE to the nation or particular geographies by deconflicting overlapping supply chain demands placed upon Members, as directed and decided by the Chairperson.

- Facilitate the efficient distribution of PPE by deconflicting overlapping distribution chain activities of Members, as directed and decided by the Chairperson.

- Create a process for and collaborate in the Allocation of PPE nationwide or in particular geographies consistent with the decisions made by the Chairperson.

- Create a process for and collaborate in meeting any other exigent requirements throughout the nation or particular geographies consistent with the overall strategy prepared by this Sub-Committee

(8) Provide data and information necessary to validate the efforts of the Sub-Committee including the actual and planned amounts of PPE to be distributed throughout the Nation, as determined by the Chairperson.

(9) Provide feedback to the Sub-Committee on the outcomes of the collective efforts of the Sub-Committee Members and any impediments or bottlenecks.

(10) Advise the Chairperson whether additional Participants or Attendees should be invited to join this Plan of Action and Sub-Committee.

(11) Carry out other activities regarding critical PPE as identified by Sub-Committees under this Plan as determined and directed by the Chairperson necessary to address the COVID-19 virus' direct threat to the national defense, where such activities have been reviewed and approved by DOJ and FTC and received concurrence from Sub-Committee members.

## **B. Information Management and Responsibilities**

FEMA will request only that data and information from Sub-Committee Participants that is necessary to meet the objectives of the Plan and consistent with the scope of the relevant Sub-Committees. Upon signing a Plan of Action Agreement for this Plan, FEMA requests that Participants endeavor to cooperate with diligence and speed, and to the extent permissible under this Plan, and share with FEMA data and information necessary to meet the objectives of this Plan.

Sub-Committee Participants agree to share with FEMA the following data with diligence and speed, to the extent permissible under this Plan, and abide by the following guidelines, where feasible and consistent with the data that is owned by each Sub-Committee Participant:

(1) In general, Participants will not be asked to share Competitively Sensitive Information directly with other Participants.

(2) FEMA will only request direct sharing of Competitively Sensitive Information among Participants during Exigent Circumstances where there is a mission critical need or timeline such that sharing only through FEMA is impractical or threatens the outcome of the Plan or Sub-Committee action. Such requests, if made, will be only among Participants whose participation is necessary to meet the objectives of the Plan,

will be limited in scope to the greatest extent possible, and will be shared only pursuant to safeguards subject to prior review and audit by DOJ and FTC. Direct sharing of Competitively Sensitive Information with other Participants will be limited in scope and circumstances to the greatest extent possible. Participants may not share Competitively Sensitive Information directly with other Participants unless specifically requested by FEMA, in consultation with DOJ and FTC. All Competitively Sensitive Information delivered to FEMA or to another Sub-Committee Participant shall be delivered by secure means, for example, password-protected or encrypted electronic files or drives with the password/key delivered by separate communication or method or via upload to an appropriately secure web portal as directed by FEMA. All data delivered to the web portal designated by FEMA is deemed to be Competitively Sensitive Information.

(3) To allow FEMA to identify and appropriately protect documents containing Competitively Sensitive Information by the Sub-Committee Participant providing the documents, the Sub-Committee Participant will make good faith efforts to designate any Competitively Sensitive Information by placing restrictive markings on documents and things considered to be competitively sensitive, the restrictive markings being sufficiently clear in wording and visibility to indicate the restricted nature of the data. The Sub-Committee Participant will identify Competitively Sensitive Information that is disclosed verbally by oral warning. Information designated as competitively sensitive will, to the extent allowed by law, be presumed to constitute trade secrets, or commercial or financial information, and be provided by the Sub-Committee Participant to FEMA with the expectation that it will be kept confidential by both parties, as such terms are understood in accordance with 5 U.S.C. § 552(b)(4) of the Freedom of Information Act and federal judicial interpretations of this statute. FEMA agrees that to the extent any information designated as competitively sensitive by a

Sub-Committee Participant is responsive to a request for disclosure under the Freedom of Information Act, FEMA will consult with the Sub-Committee Participant and afford the Participant ten (10) working days to object to any disclosure by FEMA.

(4) FEMA will make good faith efforts to appropriately recognize unmarked Documents containing Competitively Sensitive Information as Competitively Sensitive Information. However, FEMA cannot guarantee that all unmarked Documents will be recognized as being Competitively Sensitive Information and protected from disclosure to third parties. If the unmarked Documents have not been disclosed without restriction outside of FEMA, the Sub-Committee Participant may retroactively request to have appropriate designations placed on the Documents. If the unmarked Documents have been disclosed without restriction outside of FEMA, FEMA will, to the extent practicable, remove any requested information from public forums controlled by FEMA and will work promptly to request that a receiving party return or destroy disclosed unmarked Documents if requested by the Sub-Committee Participant.

(5) Competitively Sensitive Information may be used by FEMA, alone or in combination with additional information, including Documents and Competitively Sensitive Information received from third parties, to support FEMA's implementation of this Plan of Action as determined by the Chairperson. In all situations, FEMA will aggregate and anonymize Competitively Sensitive Information to the greatest extent possible to protect the interests retained by the owners of the data while still allowing the objectives of the Plan of Action and Sub-Committee to be achieved. To the greatest extent possible, such aggregation will render the competitively sensitive nature of the Competitively Sensitive Information of the Sub-Committee Participant no longer recognizable in a commercially sensitive manner, and without sufficient information to enable, by inference or otherwise, attribution to Sub-Committee Participant or its



affiliates (as clearly identified and disclosed to FEMA). Any disclosure of Competitively Sensitive Information by FEMA, within or outside a Sub-Committee, will be subject to review and approval by DOJ and FTC.

(6) Except as otherwise expressly permitted by applicable federal law, FEMA shall not disclose any Competitively Sensitive Information or use any Competitively Sensitive Information for any purpose other than in connection with the purposes of this Plan of Action, and FEMA will not sell any Competitively Sensitive Information of any Sub-Committee Participant.

(7) Except as described below, FEMA may disclose Competitively Sensitive Information only to its employees, officers, directors, contractors, agents, and advisors (including attorneys, accountants, consultants, and financial advisors). Any individual with access to Competitively Sensitive Information will be expected to comply with the terms of this Plan of Action.

a. *Information Sharing within the Sub-Committee:* FEMA may share Competitively Sensitive Information with Sub-Committee Participants and Federal Representatives of the Plan of Action, and their respective employees, officers, directors, contractors, agents, and advisors (including attorneys, accountants, consultants, and financial advisors) where there is a need to know and where disclosure is reasonably necessary in furtherance of implementing the Plan of Action. FEMA will aggregate and anonymize data prior to sharing with the Sub-Committee Participants to the greatest extent possible while still allowing the objectives of the Plan of Action to be achieved, and will not share data – particularly to competitors of the submitter – prior to consultation with and approval by the DOJ and FTC.

i. Sub-Committee Participants, when providing Competitively Sensitive Information to FEMA, may request that this Information not be shared with other Sub-

Committee Participants. Where these requests are made in good faith and are reasonable in nature, FEMA will respect these requests to the greatest extent possible and will consult the owner of the data prior to any release made to Sub-Committee Participants.

b. *Restricted Reports.* FEMA may communicate Competitively Sensitive Information to appropriate government officials through Restricted Reports. The information contained in Restricted Reports shall be aggregated and anonymized to the greatest extent possible, while recognizing that these officials may need a certain amount of granularity and specificity of information to appropriately respond to COVID-19. FEMA will aim to aggregate data to the County level, and will not share Restricted Reports prior to consultation and approval from the DOJ and FTC. FEMA may disclose Restricted Reports to relevant White House and Administration officials and State Governors, and their respective employees, officers, directors, contractors, agents, and advisors (including attorneys, accountants, consultants, and financial advisors) who have a need to know and to whom such disclosure is reasonably necessary solely in furtherance of the implementation of this Plan of Action. FEMA shall take appropriate action (by instructions, agreement, or otherwise) to ensure that receiving parties comply with all data-sharing confidentiality and obligations under this Plan of Action as if such persons or entities had been parties to this Plan of Action.

c. *Public Reports.* FEMA may share information with the public through Public Reports. Data contained in Public Reports shall be fully aggregated and anonymized. Public Reports shall be aggregated to at least a state level and may be publicly disclosed after consultation and approval from the DOJ and FTC.

(8) Where possible and not obviated by Exigent Circumstances, FEMA will notify Sub-Committee Participants prior to the release of any Competitively Sensitive Information that has not been fully aggregated and anonymized. In consultation with

DOJ and FTC, FEMA will consider any good-faith requests made by Sub-Committee members to hold the release of data or requests for further aggregation or anonymization. In general, FEMA will not provide notification prior to the release of *Public Reports*, under the presumption that the data in these reports has already been fully anonymized and de-identified.

(9) Any party receiving Competitively Sensitive Information through this Plan shall use such information solely for the purposes outlined in the Plan and take steps, such as imposing previously approved firewalls or tracking usage, to prevent misuse of the information. Disclosure and use of Competitively Sensitive Information will be limited to the greatest extent possible, and any party receiving Competitively Sensitive Information shall follow the procedures outlined in paragraph 7 above.

(10) At the conclusion of a Participant's involvement in a Plan – due to the deactivation of the Plan or due to the Participant's withdrawal or removal – each Participant will be requested to sequester any and all Competitively Sensitive Information received through participation in the Plan. This sequestration shall include the deletion of all Competitively Sensitive Information unless required to be kept pursuant to the Record Keeping requirements as described *supra*, Section I, 44 CFR part 332, or any other provision of law.

### **C. Oversight**

Each Sub-Committee Chairperson is responsible for ensuring that the Attorney General, or suitable delegate(s) from the DOJ, and the FTC Chairman, or suitable delegate(s) from the FTC, have awareness of activities under this Plan, including activation, deactivation, and scheduling of meetings. The Attorney General, the FTC Chairman, or their delegates may attend Sub-Committee meetings and request to be apprised of any activities taken in accordance with activities under this Plan. DOJ or

FTC Representatives may request and review any proposed action by the Sub-Committee or Sub-Committee Participants undertaken pursuant to this Plan, including the provision of data. If any DOJ or FTC Representative believes any actions proposed or taken are not consistent with relevant antitrust protections provided by the DPA, he or she shall provide warning and guidance to the Sub-Committee as soon as the potential issue is identified. If questions arise about the antitrust protections applicable to any particular action, FEMA may request DOJ, in consultation with the FTC, provide an opinion on the legality of the action under relevant DPA antitrust protections.

## **VI. Establishment of the Sub-Committees**

This Plan establishes Sub-Committees to implement the Plan to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Personal Protective Equipment (PPE) to Respond to COVID-19 to provide the Federal Government and the Participants a forum to maximize the manufacture and efficient distribution of selected types of critical PPE and to create a prioritization protocol based upon identified types of PPE End-Users and their demonstrated or projected requirements, and demonstrated or projected geographic and regional areas of need. The outcome should include a framework to expeditiously meet any PPE needs in Exigent Circumstances anywhere in the Nation, and to ensure that actions to support PPE stockpiling and reserves do not interfere with immediate requirements that would result in an unacceptable risk to healthcare providers or other potential PPE recipients. A Sub-Committee Chairperson designated by the Chairperson will convene and preside over each Sub-Committee. Sub-Committees will not be used for contract negotiations or contract discussions between the Participants and the Federal Government; such negotiations or discussions will be in accordance with applicable federal contracting policies and procedures. However, this shall not limit any discussion within a Sub-

Committee about the operational utilization of existing and potential contracts between the Participants and Representatives when seeking to align their use with overall manufacturing and distribution efforts consistent with this Plan.

Each Sub-Committee will consist of designated Representatives from FEMA, HHS, other federal agencies with equities in this Plan, and each Sub-Committee Participant. The Attorney General and Chairman of the FTC, or their delegates, may also join each Sub-Committee and attend meetings at their discretion. Attendees may also be invited at the discretion of a Sub-Committee Chairperson as subject matter experts, to provide technical advice, or to represent other government agencies, but will not be considered part of the Sub-Committee.

To the extent necessary to respond to the Pandemic, only at the explicit direction of a Sub-Committee Chairperson, and subject to the provisions of Section V(B), Sub-Committee Members may be asked to provide technical advice, share information, help identify and validate places and resources of the greatest need, help project future manufacturing and distribution demands, assist in identifying and resolving the allocation of scarce resources amongst all necessary public and private sector domestic needs under Exigent Circumstances, and take any other necessary actions to maximize the timely manufacture and distribution of PPE as determined necessary by FEMA to respond to the Pandemic. A Sub-Committee Chairperson or his or her designee, at the Sub-Committee Chairperson's sole discretion, will make decisions on these issues in order to ensure the maximum efficiency and effectiveness in the use of Sub-Committee Member's resources. All Sub-Committee Participants will be invited to open Sub-Committee meetings. For selected Sub-Committee meetings, attendance may be limited to designated Sub-Committee Participants to meet specific operational requirements, as determined by FEMA.

Each Sub-Committee Chairperson shall notify the Attorney General, the Chairman of the FTC, Representatives, and Participants of the time, place, and nature of each meeting and of the proposed agenda of each meeting to be held to carry out this Plan of Action. Additionally, each Sub-Committee Chairperson shall provide for publication in the *Federal Register* of a notice of the time, place, and nature of each meeting. If a meeting is open, a *Federal Register* notice will be published reasonably in advance of the meeting. A Sub-Committee Chairman may restrict attendance at meetings only on the grounds outlined by 44 CFR 332.5(c)(1)-(3). If a meeting is closed, a *Federal Register* notice will be published within ten (10) days of the meeting and will include the reasons why the meeting is closed pursuant to 44 CFR 332.3(c)(2).

The Sub-Committee Chairperson shall establish the agenda for each meeting, be responsible for adherence to the agenda, and provide for a written summary or other record of each meeting and provide copies of transcripts or other records to FEMA, the Attorney General, the Chairman of the FTC, and all Sub-Committee Participants. The Chairperson shall take necessary actions to protect from public disclosure any data discussed with or obtained from Sub-Committee Participants which a Sub-Committee Participant has identified as a trade secret or as privileged and confidential in accordance with DPA sections 708(h)(3) and 705(d), or which qualifies for withholding under 44 CFR 332.5.

## **VII. Application and Agreement**

The Sub-Committee Participant identified below hereby agrees to join in the Federal Emergency Management Agency sponsored Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Personal Protective Equipment (PPE) under the Voluntary Agreement for the Manufacture and Distribution of Healthcare Resources Necessary to Respond to a Pandemic and to

become a Participant in one or more Sub-Committees established by this Plan. This Plan will be published in the *Federal Register*. This Plan is authorized under section 708 of the Defense Production Act of 1950, as amended. Regulations governing the Voluntary Agreement for the Manufacture and Distribution for the Manufacture and Distribution of Healthcare Resources Necessary to Respond to a Pandemic and all subsequent Plans of Action appear at 44 CFR part 332. The applicant, as a Sub-Committee Participant, agrees to comply with the provisions of section 708 of the Defense Production Act of 1950, as amended, the regulations at 44 CFR part 332, and the terms of this Plan.

#### **VIII. Assignment**

No Sub-Committee Participant may assign or transfer this Plan, in whole or in part, or any protections, rights or obligations hereunder without the prior written consent of the Sub-Committee Chairperson. When requested, the Sub-Committee Chairperson will respond to written requests for consent within 10 (ten) business days of receipt.

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(Company name)

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(Name of authorized representative)

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(Signature of authorized representative)

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(Date)

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Sub-Committee Chairperson

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(Date)

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**Pete Gaynor,**

*Administrator,*

*Federal Emergency Management Agency.*

[FR Doc. 2020-26986 Filed: 12/7/2020 8:45 am; Publication Date: 12/8/2020]